Vaxart Announces Publication Demonstrating the Immunogenicity and Safety of its First-Generation Oral Pill Norovirus Vaccine Candidate in Elderly Adults

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Robust, antigen-specific responses in the nasal cavity following oral administration underscore the efficiency of Vaxart's oral vaccine platform in generating mucosal antibody responses beyond the site of administration

SOUTH SAN FRANCISCO, Calif., March 05, 2025 (GLOBE NEWSWIRE) -- Vaxart, Inc. (Nasdaq: VXRT) today announced that complete data from the Phase 1b trial of its first-generation oral pill norovirus vaccine candidate in elderly adults (55-80 years) (NCT04854746) have been published in *Science Translational Medicine*. The data, which show strong and durable antibody responses and induction of norovirus-specific antibody and T cell responses, support immunogenicity of the vaccine candidate in a patient population that often has age-related reductions in immune responses to injected vaccines.[1,2] Norovirus is a highly contagious virus that causes acute gastroenteritis (AGE) and can lead to substantial morbidity in older adults.[3]

"A key finding of this study evaluating our first-generation oral pill norovirus vaccine candidate in elderly individuals was that the antibody and serum responses observed in these participants were robust and durable, and a cross-study analysis suggested that the observed antibody and cellular responses were independent of age. These findings are encouraging given that older adults have an increased risk of norovirus-related morbidity and may have less robust immune responses following vaccination compared with younger individuals," said James F. Cummings, MD, Chief Medical Officer at Vaxart. "Another key result was that an orally-administered vaccine can generate potent antibody responses in mucosal tissues outside the gastrointestinal tract, which could have important implications for use of our vaccine platform for norovirus and other indications as well."

The Phase 1b study evaluated the safety and immunogenicity of Vaxart's oral norovirus vaccine candidate in two groups of healthy older adults aged 55-65 and 66-80 years old. The vaccine was administered orally at three dose levels by prime and boost, 28 days apart. Participants were randomized to receive vaccine or placebo at a 2:1 ratio, and 63 volunteers completed the study, which included safety and immunogenicity assessments through day 390.

Key findings from the study include:

- The vaccine candidate generated robust and durable serum antibody responses, with all three dose cohorts demonstrating statistically significant increases in serum anti-VP1 IgA compared to the placebo cohort on day 29 and day 57. No statistically significant differences were found between the two age groups within each dosing cohort.
- Dose-dependent increases in vaccine-induced responses were also observed for serum anti-VP1 IgG in all vaccinated cohorts on day 29 and day 57 compared to pre-vaccination levels.
- The vaccine induced VP1-specific IgA mucosal-homing antibody-secreting B cells and this response was independent of age.
- The high-dose vaccine induced mucosal-homing T cells, which may contribute to protection against persistent infections.
- Oral administration of the vaccine stimulated strong and durable IgA responses in saliva and the nasal cavity.
- Overall, the vaccine was safe and well tolerated in older adults. All solicited events were mild to moderate, with no grade 3 events related to the vaccine. Headache (14%) and malaise/fatigue (16%) were the most common solicited symptoms reported in the week following vaccine administration; headache (14%) and malaise/fatigue (14%) were reported at similar rates in the placebo group.

"The results of this clinical trial suggest that our oral pill norovirus vaccine program may be uniquely positioned to protect elderly individuals from adverse norovirus infection outcomes," said Steven Lo, Chief Executive Officer at Vaxart. "These patients are at higher risk of severe AGE but also respond less effectively to injected vaccines. Additionally, most approved mucosal vaccines are not recommended for older individuals due to safety concerns. While early stage, the data reported today suggest that our candidate may prove to safely provide the benefits of a mucosal vaccine to patients at higher risk of adverse norovirus outcomes."

Vaxart previously reported that a Phase 2 challenge study of an oral pill norovirus vaccine candidate produced a statistically significant reduction in infection rate, a non-statistically significant reduction in norovirus AGE and a substantial reduction in viral shedding. A Phase 1 study in lactating mothers showed that the Company's vaccine candidate resulted in a 4-6-fold increase in norovirus antibodies in breast milk, which may help to protect infants through passive antibody transfer. In January 2025, Vaxart announced that the next step in its norovirus program will be a Phase 1, open label, dose ranging clinical trial evaluating its second-generation oral norovirus vaccine constructs head-to-head against its first-generation constructs. This trial is expected to initiate in the first half of 2025.

References

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2. A. Pera, C. Campos, N. López, F. Hassouneh, C. Alonso, R. Tarazona, R. Solana, Immunosenescence: Implications for response to infection and vaccination in older people. *Maturitas* **82**, 50-55 (2015).
3. A. J. Hall, R. I. Glass, U. D. Parashar, New insights into the global burden of noroviruses and opportunities for prevention. *Expert Rev Vaccines* **15**, 949-951 (2016).

About Vaxart

Vaxart is a clinical-stage biotechnology company developing a range of oral recombinant vaccines based on its proprietary delivery platform. Vaxart vaccines are designed to be administered using pills that can be stored and shipped without refrigeration and eliminate the risk of

needle-stick injury. Vaxart believes that its proprietary pill vaccine delivery platform is suitable to deliver recombinant vaccines, positioning the company to develop oral versions of currently marketed vaccines and to design recombinant vaccines for new indications. Vaxart's development programs currently include pill vaccines designed to protect against coronavirus, norovirus and influenza, as well as a therapeutic vaccine for human papillomavirus (HPV), Vaxart's first immune-oncology indication. Vaxart has filed broad domestic and international patent applications covering its proprietary technology and creations for oral vaccination using adenovirus and TLR3 agonists.

Note Regarding Forward-Looking Statements
This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this press release regarding Vaxart's strategy, prospects, plans and objectives, results from preclinical and clinical trials and the timing of such results, commercialization agreements and licenses, and beliefs and expectations of management are forward-looking statements. These forward-looking statements may be accompanied by such words as "should," "believe," "could," "potential," "will," "expected," “anticipate,” "plan," and other words and terms of similar meaning. Examples of such statements include, but are not limited to, statements relating to Vaxart's ability to develop and commercialize its product candidates, Vaxart's expectations regarding clinical results and trial data, and the timing of receiving and reporting such clinical results and trial data; and Vaxart's expectations with respect to the effectiveness of its product candidates. Vaxart may not actually achieve the plans, carry out the intentions, or meet the expectations or projections disclosed in the forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations, and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Vaxart makes, including uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement, and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates, and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; decisions by regulatory authorities impacting labeling, manufacturing processes, and safety that could affect the availability or commercial potential of any product candidate, including the possibility that Vaxart's product candidates may not be approved by the FDA or non-U.S. regulatory authorities; that, even if approved by the FDA or non-U.S. regulatory authorities, Vaxart's product candidates may not achieve broad market acceptance; that a Vaxart collaborator may not attain development and commercial milestones; that Vaxart or its partners may experience manufacturing issues and delays due to events within, or outside of, Vaxart's or its partners' control; difficulties in production, particularly in scaling up initial production, including difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel or key raw materials, and compliance with strictly enforced federal, state, and foreign regulations; that Vaxart may not be able to obtain, maintain, and enforce necessary patent and other intellectual property protection; that Vaxart's capital resources may be inadequate; Vaxart's ability to resolve pending legal matters; Vaxart's ability to obtain sufficient capital to fund its operations on terms acceptable to Vaxart, if at all; the impact of government healthcare proposals and policies; competitive factors; and other risks described in the "Risk Factors" sections of Vaxart's Quarterly and Annual Reports filed with the SEC. Vaxart does not assume any obligation to update any forward-looking statements, except as required by law.

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